Docket No. DEP5050USPCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Richard Farrar et al — Confirmation No.: 2006

Appln. No.: 10/566,147 — Art Unit : 3738

Filed : August 4, 2009 — Examiner : Stewart, Jason-Dennis Neilken

Title : KNEE JOINT PROSTHESIS

CERTIFICATE OF TRANSMISSION			
I hereby certify that this correspondence is being electronically filed via EFS-Web to the Commissioner for Patents with the U.S. Patent and Trademark Office on.			
Name	Brian S. Tomko		
Signature		Date	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

1.132 Declaration of Liam Rowley

I, Liam Rowley, having a work address of Number One Building, White Rose Office Park, Leeds hereby declare as follows:

1. I am a Group Manager of Knee Development at DePuy International Limited, and my responsibilities now and in the past have included new product development and support for orthopaedic implants and instruments, including knee implants and instruments. I have worked at DePuy International Limited for more than 8 years and we have been developing knee implants throughout the duration of my employment with DePuy International Limited.

2. I obtained a Bachelor of Engineering Honors Degree from Leeds Metropolitan University in 1994 and a Master of Science Degree in Medical and Life Science Engineering from Leeds University in 2007.

3. I am one of a group of inventors of the claimed subject matter of the above-

referenced application, and as such have read and understand the information disclosed and claimed therein.

4. The above-referenced patent application is directed to a knee joint prosthesis.

5. I have also read U.S. Patent No. 4,298,992 ("Burstein") and fully understand the inventions disclosed therein. Burstein was cited in the Office Action mailed on June 25, 2010.

6. At the request of counsel, the flex angles of the knee implant depicted in Burstein were determined. First, Burstein notes at column 3, lines 14-17 that: "FIGS. 7A to 7F are side cross-sectional views in generally schematic form showing the assembled components in various positions (corresponding to a range of leg articulation from full extension to full flexion)". Figure 7A thus corresponds to a position where the leg is in full extension and Figure 7F corresponds to a position where the leg is in full flexion. Burstein at column 4, lines 30-32 further states: "With the leg extended (FIG. 7A) a generally stable position is established by nesting of the femoral condyles in the tibial plateau concavities." It is well understood in the art that full extension represents a position of zero flexion or where the flex angle is zero. Thus, as Figure 7A corresponded to the full extension position of the Burstein implant, a datum angle of 0 degrees was assigned to the position of the femoral and tibial implant components of that figure.

7. Any further extension beyond full extension is referred to as hyperextension or negative flexion. Burstein acknowledges that, while Figure 7A does not depict hypertension, the interaction of the femoral and tibial components of the implant when in a hypertension position can be understood by viewing Figure 7A. See Burstein, col 4:62-67 ("If the knee should undergo a fairly large hyperextension (not shown, but see FIG. 7A), say about 15°, the anterior part of the superior wall 16a of the femoral recess 16 will roll back into engagement with the anterior surface of the tibial post and prevent posterior dislocation of the femur.").

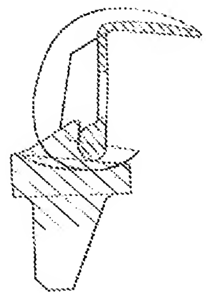
8. With the datum of 0° assigned to Figure 7A, the method of determining the flexion or flex angle for each of the other Figures 7B-7F is readily accomplished by measuring the rotation of any one of the straight line surfaces on the femoral component and taking an angular measurement with reference to a datum surface, for example, on the underside of the tibia, which remains horizontal throughout each of Figures 7A-7F. The most readily usable straight line surfaces of the femoral component are the distal resection surface or the posterior resection surface.

9. A simple manual method with overlays, pencil line extensions and a protractor, or a more elaborate cad/electronic method easily provide the angular change of the chosen femoral surface as compared with the datum tibial surface. A manual method was performed and the flex angle depicted in Figure 7B was determined to be 30°; the flex angle depicted in Figure 7C was determined to be 45°; the flex angle depicted in Figure 7D was determined to be 60°; the flex angle depicted in Figure 7E was determined to be 90°; and the flex angle depicted in Figure 7F was determined to be 118°.

10. In order to study how the surface area of contact of the post bearing surface of the tibial component and the cam surface of the femoral component changes when the flex angle is greater than 120°, the flex angle was varied between the femoral and tibial components using a methodology like that used to measure the flex angles of the figures depicted in Burstein, and the surface area of contact (as viewed from a side cross-sectional view) between the post bearing surface and the cam surface was observed.

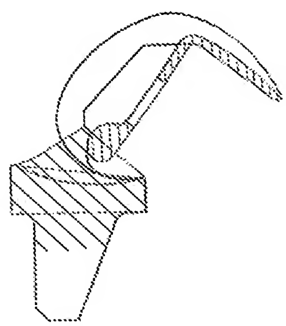
11. To rotate the femoral component to a desired angle relative to the tibial component, the femoral component and tibial component are depicted separately and are brought together, maintaining the desired angle, such that the posterior aspect of the femoral condyle and the curved tibial bearing come into contact, at this point there being a tangency between the two curves. This is done by depicting the tibial aspect on paper and the femoral on clear plastic overlay. The femoral component is then moved anteriorly, maintaining the desired angle and the main bearing tangency until such point that the cam of the femoral component contacts the posterior aspect of the post of the tibial component. At this position, the femoral component is maintained at the desired angle, there is tangency contact between the femoral and tibial main bearings, and the cam and post contact one another, thereby forming a "three legged stool". Using this method, there is only one possible position for any desired angle.

12. Using the above-described method, it was determined that the maximum surface area of contact defined by the tibial component and the cam of Burstein is achieved at approximately 100°. See the figure below, where the femoral component of Burstein has been rotated to show how the surfaces would engage at 100 degrees. At this position, the medial and lateral condyles are relatively fully engaged with the tibial component and the cam shown as element 20 (in the Burstein figures) is fully engaged with cam surface 42a of post 42.



100°

13. To understand how the surface area of contact between the cam and the post surface of Burstein changes as the femoral component is rotated above 120°, the femoral component was rotated relative to the tibial component to a flex angle of 130°, as depicted below.



130°

14. It was noted that as the femoral component rotates from 100° to 118° (as shown in Figure 7E of Burstein) to the above-depicted position at 130°, the cam 20 moves up the post 42 and the anterior aspects of the medial and lateral condyles lift off of the tibial component surface. As the knee flexes from 100° to 130°, the cam moves up the post, and the surface area of contact between the cam of the femoral component and the post surface of the tibial component decreases. Thus, the area of contact between the post bearing surface and the cam surface of Burstein decreases from its approximate maximum at 100° to something less than its maximum surface area of contact at 118°, and less still as the knee is flexed to an angle greater than 120°, for example, to a flex angle of 130°.

15. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the patent application or any patent issuing thereon.

Date: 23 DEC 2010

Liam Rowley